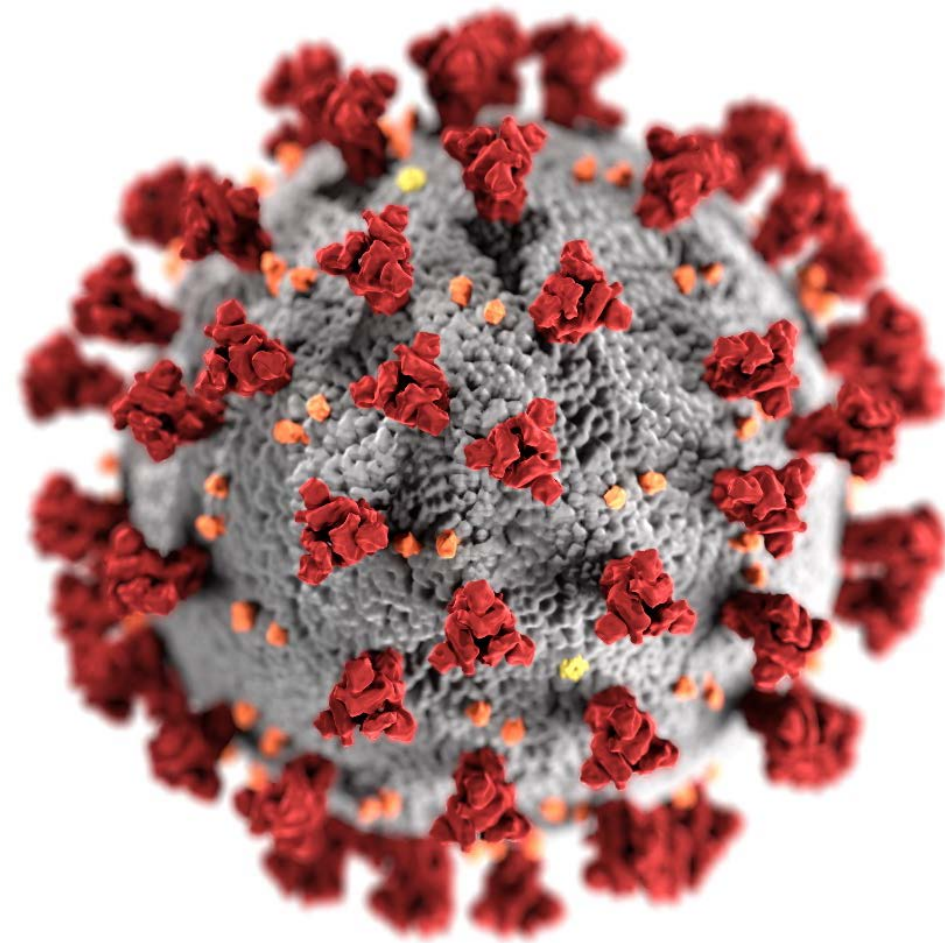


Exhibit QQ

COVID-19 Vaccines in Adults: Benefit-Risk Discussion

Hannah Rosenblum, MD
ACIP Meeting
July 22, 2021



cdc.gov/coronavirus

Current COVID-19 vaccine policy

- Today's discussion will focus on the benefits and harms of COVID-19 vaccines in adults
- Three COVID-19 vaccines are recommended for persons aged 18 years and older in the United States under FDA's Emergency Use Authorization

Benefits and risks by vaccine, age and sex in adults

Benefits of COVID-19
Janssen and mRNA
vaccines in adults

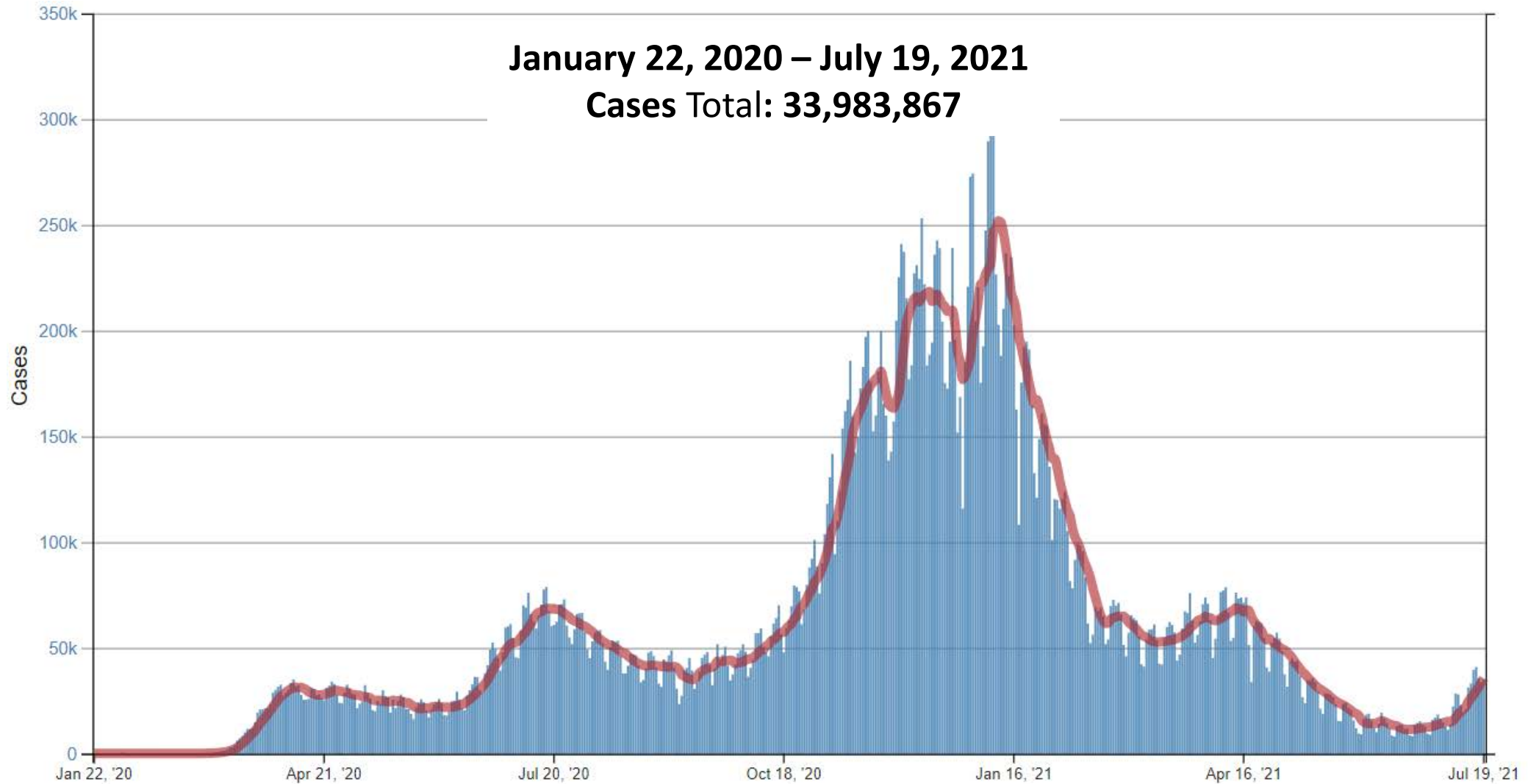


Risk after COVID-19
Janssen and mRNA
vaccines in adults

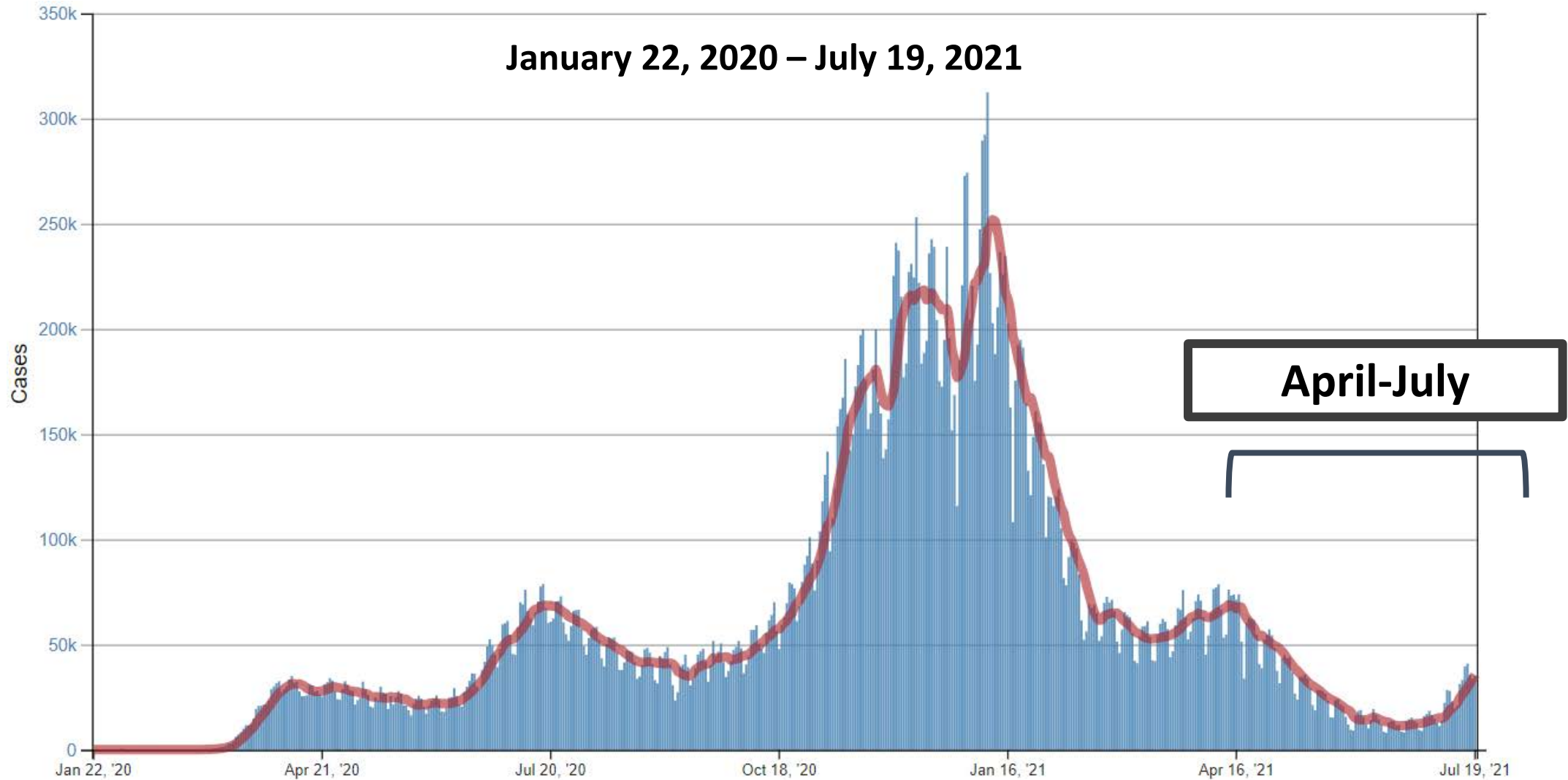
COVID-19 vaccines in adults: Benefit-risk discussion

- Public health problem
 - Recent COVID-19 epidemiology in adults
 - Adverse events reported after vaccination
 - Guillain-Barre Syndrome (GBS)
 - Thrombosis with Thrombocytopenia Syndrome (TTS)
 - Myocarditis
- Benefit/Risk assessment
 - Benefits of Janssen vaccine
 - Risk of GBS after Janssen vaccine
 - Risk of TTS after Janssen vaccine
 - Benefits of mRNA vaccines
 - Risk of myocarditis after mRNA vaccines

Trends in number of U.S. COVID-19 cases reported to CDC

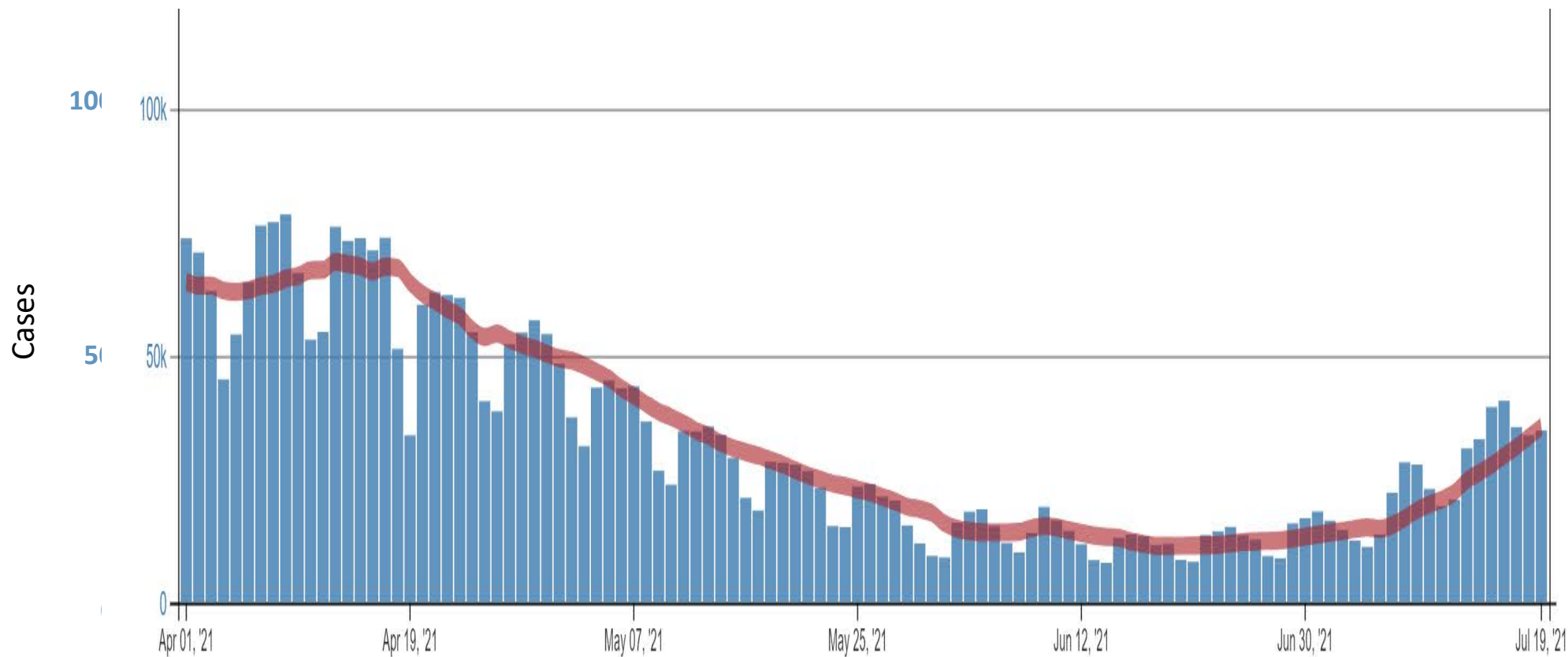


Trends in number of U.S. COVID-19 cases reported to CDC



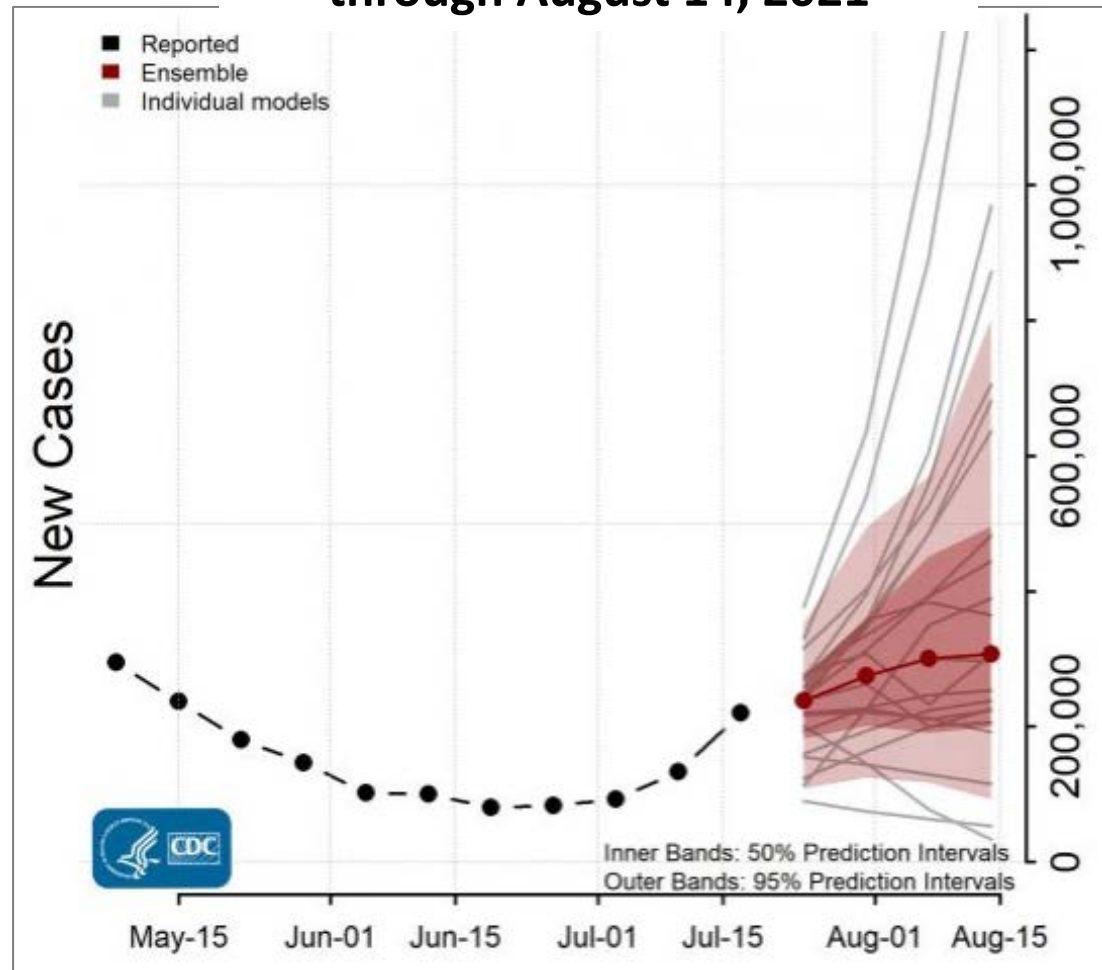
Recent trends in number of U.S. COVID-19 cases

April 1, 2020 – July 19, 2021

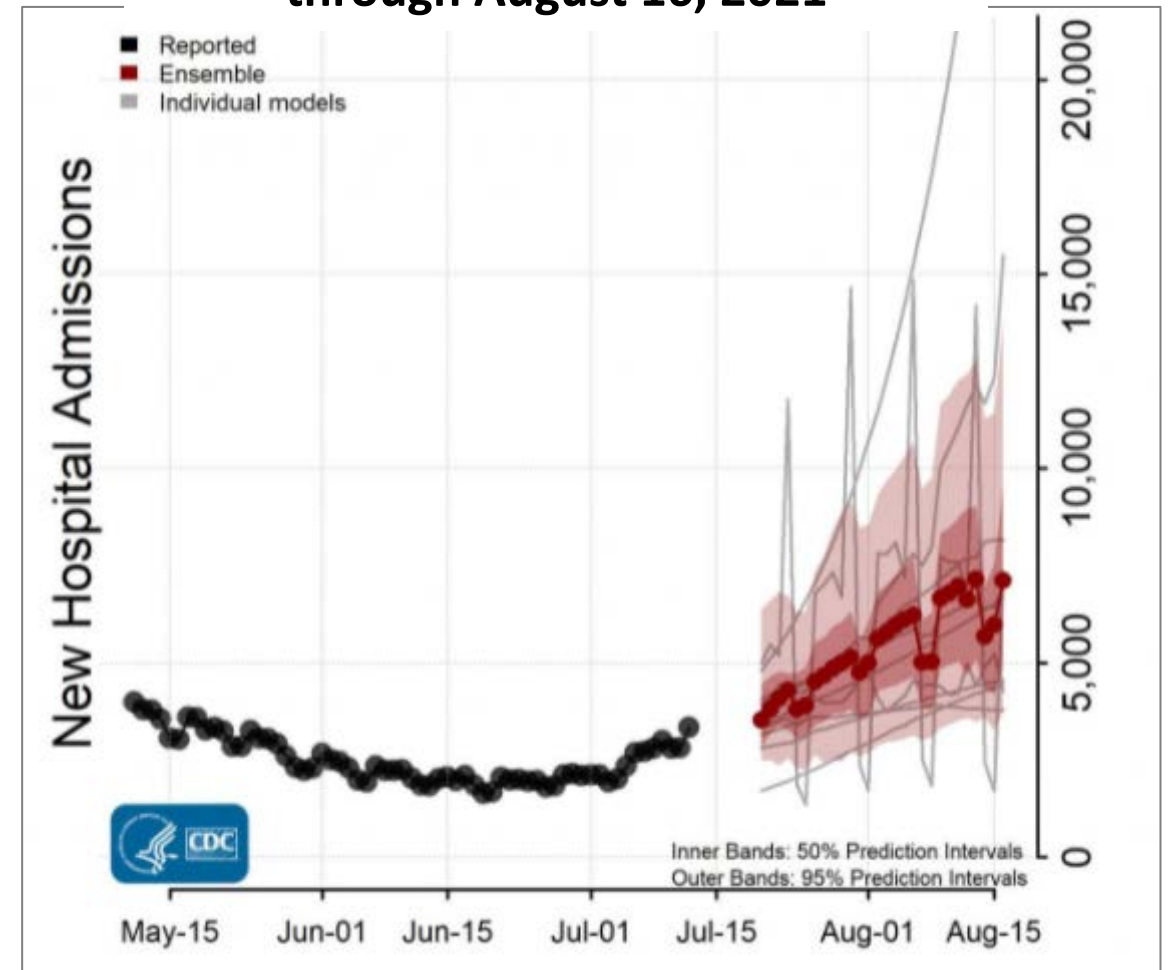


Forecast of cases and hospitalizations for the next four weeks

**New COVID-19 cases forecasted
through August 14, 2021**

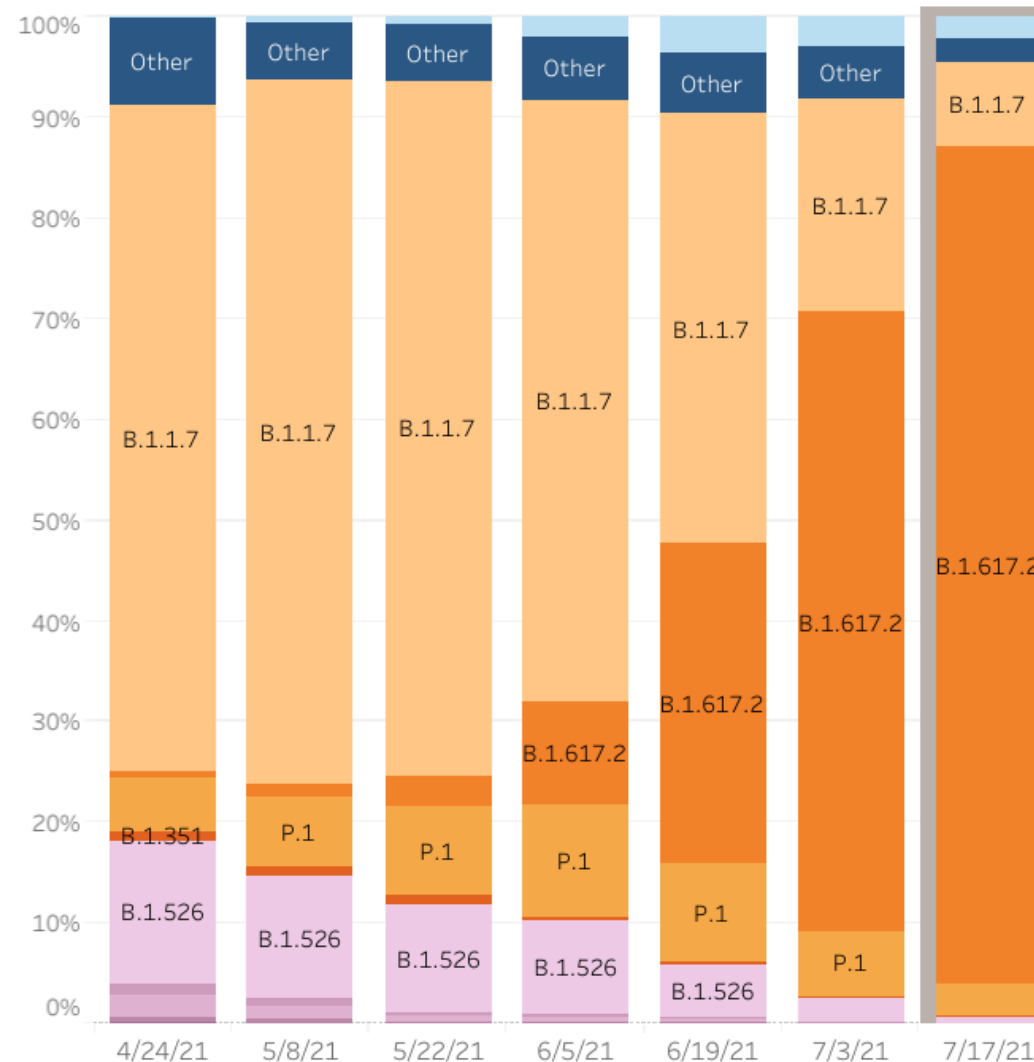


**COVID-19 hospitalizations forecasted
through August 16, 2021**



SARS-CoV-2 variants circulating in the United States

April 11 – July 17, 2021



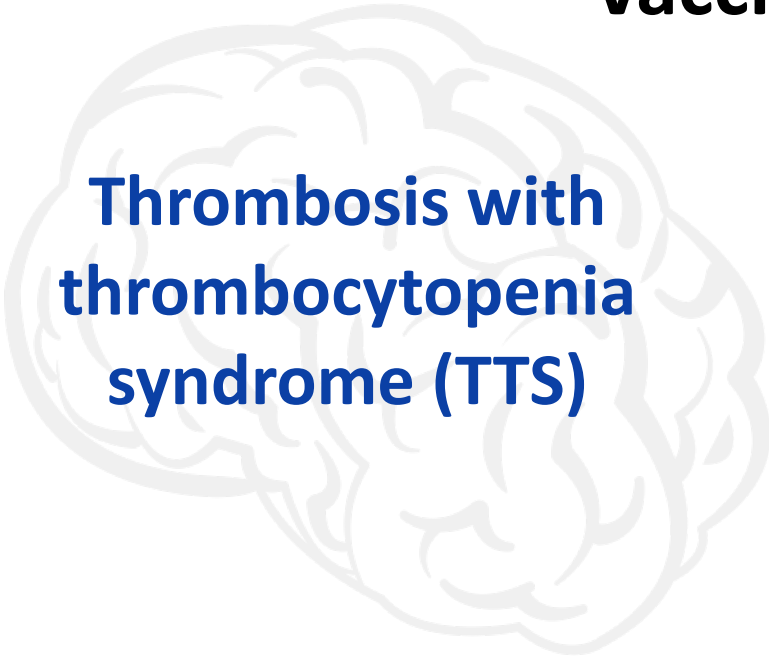
Alpha (B.1.1.7): 8%

**Delta (B.1.617.2):
83.2%**

Gamma (P.1): 3%

Rare serious adverse events reported after COVID-19 vaccination

Janssen vaccine



**Thrombosis with
thrombocytopenia
syndrome (TTS)**



**Guillain-Barré
syndrome (GBS)**

mRNA vaccines



Myocarditis

Summary

- After a period of decline, COVID-19 cases and hospitalizations have begun to increase in recent weeks.
 - Variants continue to spread; Delta variant now found in >80% of cases in the United States

- Rare events have been observed after COVID-19 vaccination:
 - Janssen vaccine: TTS & GBS
 - mRNA vaccine: myocarditis

Benefits and Harms of Janssen COVID-19 Vaccine



Methods for assessment of benefit-risk balance – Janssen vaccine

Benefits

- Expected protection provided per 1 million Janssen vaccine doses by age/sex calculated using:
 - Most recent case incidence, COVID-NET hospitalization & severity data (through June 19th)
 - VE (90%) for hospitalization
 - VE (66%) for COVID-19 symptomatic cases
 - 120-day period



Methods for assessment of benefit-risk balance – Janssen vaccine

Benefits

- Expected protection provided per 1 million Janssen vaccine doses by age/sex calculated using:
 - Most recent case incidence, COVID-NET hospitalization & severity data (through June 19th)
 - VE (90%) for hospitalization
 - VE (66%) for COVID-19 symptomatic cases
 - 120-day period



Potential harms

- Estimated cases of **GBS** per 1 million Janssen vaccine doses, by age/sex using cases from VAERS through June 30, 2021
- Estimated cases of **TTS** per 1 million Janssen vaccine doses, by age/sex using cases reported to VAERS through July 8, 2021

Benefits of the Janssen COVID-19 vaccine

- The clinical trial demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19. Overall efficacy was **66%**
- Against **severe** outcomes:
 - Vaccine efficacy against COVID-19-associated **hospitalization: 93%**
 - VE against **deaths** due to COVID-19: **100%**
- Persistence of antibody response & activity demonstrated against a variety of variants^{*}

^{*}Durable humoral and cellular immune responses months after Ad26.COV2.S vaccination NEJM https://www.nejm.org/doi/full/10.1056/NEJMc2108829?query=featured_home

Potential Harms of the Janssen COVID-19 vaccine: Guillain-Barré Syndrome

- 12.6 million vaccine doses administered* and 98 GBS cases as of June 30, 2021

	Females n= 37			Males n=61		
Age group	Cases	Doses admin	Reporting rate [†]	Cases	Doses admin	Reporting rate [†]
18-29 years old	1	1,037,996	1.0 per million	3	1,258,963	2.4 per million
30-49 years old	13	1,957,663	6.6 per million	18	2,407,430	7.5 per million
50-64 years old	14	1,888,715	7.4 per million	33	2,115,411	15.6 per million
65+ years old	9	1,037,996	8.7 per million	7	932,764	7.5 per million

* Source of doses administered: FDA, through June 30, 2021; Some age- and sex-specific dose administered data were imputed

[†] Reporting rate = GBS cases per 1 million Janssen COVID-19 vaccine doses administered

GBS = Guillain-Barré Syndrome

Potential Harms of the Janssen COVID-19 vaccine:

Thrombosis with Thrombocytopenia Syndrome

- 12.5 million vaccine doses administered* and 38 confirmed TTS cases as of July 8, 2021

	Females n= 28			Males n=10		
Age group	Cases	Doses admin	Reporting rate [†]	Cases	Doses admin	Reporting rate [†]
18-29 years old	4	946,358	4.2 per million	3	1,281,479	2.3 per million
30-49 years old	17	1,934,574	8.8 per million	4	2,440,773	1.6 per million
50-64 years old	7	1,865,372	3.8 per million	3	2,130,473	1.4 per million
65+ years old	0	1,028,190	0.0 per million	0	943,098	0.0 per million


* Source of doses administered: <https://covid.cdc.gov/covid-data-tracker/#vaccinations> through July 8, 2021; Some age- and sex-specific doses administered data were imputed

[†] Reporting rate = TTS cases per 1 million Janssen COVID-19 vaccine doses administered

TTS=Thrombosis with Thrombocytopenia Syndrome

Estimated predicted COVID-19 cases prevented vs. GBS cases for every million Janssen vaccinations over 120 days

Females 18–29 Years

 **8,900** COVID-19 cases prevented

 **700** hospitalizations prevented


 **50** ICU admissions prevented
5 deaths prevented

1 GBS case

Males 18–29 Years

 **6,600** COVID-19 cases prevented


 **300** hospitalizations prevented

 **60** ICU admissions prevented
3 deaths prevented

2 GBS cases

Estimated predicted COVID-19 cases prevented vs. GBS & TTS cases for every million Janssen vaccinations over 120 days

Females 18–29 Years

 **8,900** COVID-19 cases prevented

 **700** hospitalizations prevented


 **50** ICU admissions prevented
5 deaths prevented

1 GBS case
4-5 TTS cases

Males 18–29 Years

 **6,600** COVID-19 cases prevented

 **300** hospitalizations prevented

 **60** ICU admissions prevented
3 deaths prevented

2 GBS cases
2-3 TTS cases

Estimated predicted COVID-19 cases prevented vs. GBS & TTS cases for every million Janssen vaccinations over 120 days

Females 30–49 Years

 **10,100** COVID-19 cases prevented

 **900** hospitalizations prevented

 **140** ICU admissions prevented

20 deaths prevented

6-7 GBS cases
8-10 TTS cases

Males 30–49 Years

 **7,600** COVID-19 cases prevented

 **650** hospitalizations prevented

 **150** ICU admissions prevented

25 deaths prevented

7-8 GBS cases
1-2 TTS cases

Estimated predicted COVID-19 cases prevented vs. GBS & TTS cases for every million Janssen vaccinations over 120 days

Females 50–64 Years

 **12,100** COVID-19 cases prevented

 **1,600** hospitalizations prevented

 **350** ICU admissions prevented

120 deaths prevented


7-8 GBS cases

3-4 TTS cases

Males 50–64 Years

 **10,100** COVID-19 cases prevented

 **1,800** hospitalizations prevented

 **480** ICU admissions prevented

140 deaths prevented

14-17 GBS cases

1-2 TTS cases

Estimated predicted COVID-19 cases prevented vs. GBS & TTS cases for every million Janssen vaccinations over 120 days

Females 65+ Years

 **29,000** COVID-19 cases prevented

 **5,900** hospitalizations prevented

 **1,250** ICU admissions prevented

840 deaths prevented

8-10 GBS cases
0 TTS cases

Males 65+ Years

 **36,600** COVID-19 cases prevented

 **11,800** hospitalizations prevented

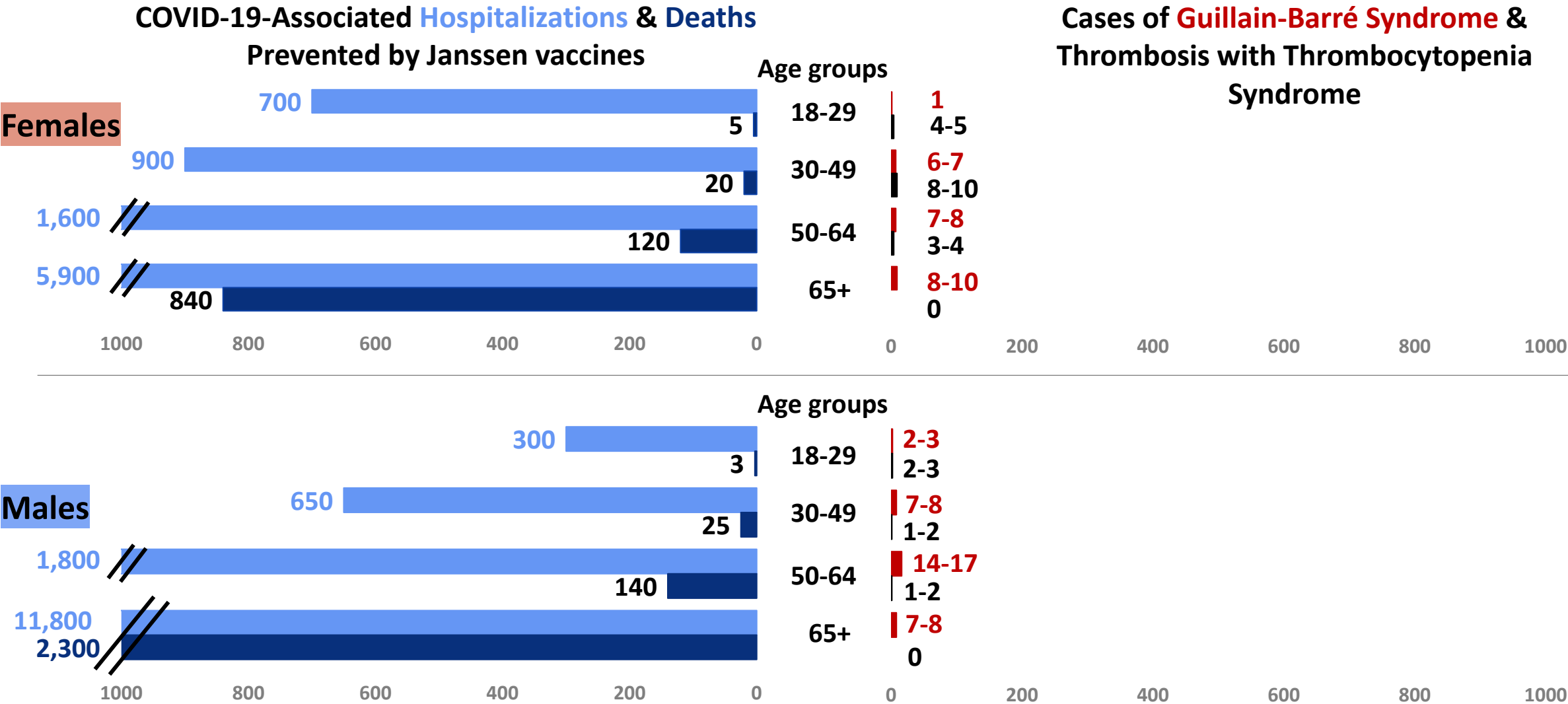
 **3,300** ICU admissions prevented

2,300 deaths prevented

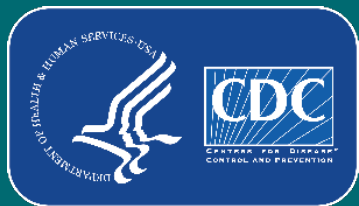
7-8 GBS cases
0 TTS cases

Benefits and risks after Janssen vaccine, by age group & sex

For every million doses of vaccine given with US exposure risk and hospitalization rates from June 19, 2021



Benefits and Harms of mRNA COVID-19 Vaccines



Methods for assessment of benefit-risk balance – mRNA COVID-19 vaccines in adults

Benefits

- Expected protection provided per 1 million mRNA vaccine doses using:
 - Most recent case incidence, COVID-NET hospitalization and severity data (through June 19th)
 - VE for hospitalization (95%)
 - VE for COVID-19 symptomatic cases (95%)
 - 120-day period



Potential harms

- Estimated cases of **myocarditis** per 1 million second doses of mRNA COVID-19 vaccine, by age/sex using data from VAERS through June 30, 2021

Benefits of mRNA vaccines

- Clinical trial data demonstrated high efficacy against symptomatic, laboratory-confirmed COVID-19 among adults with both mRNA vaccines (Pfizer-BioNTech and Moderna)
 - Overall efficacy was **94-95%**
 - Vaccine efficacy against COVID-19 associated hospitalization was **89-100%**
- Persistence of antibody response & activity demonstrated against a variety of variants*

Polack FP et al. N Engl J Med 2020; DOI: 10.1056/NEJMoa2034577; Frenck RW et al. N Engl J Med 2021; DOI: 10.1056/NEJMoa2107456;

Baden LR et al. N Engl J Med 2021; DOI: 10.1056/NEJMoa2035389

*<https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>

Potential Harms of the mRNA COVID-19 vaccines:

Myocarditis

- 141 million 2nd mRNA vaccine doses administered* and 497 myocarditis cases as of June 30, 2021 in age 18+

	Females n= 105			Males n= 392		
Age group	Cases	Doses admin	Reporting rate [†]	Cases*	Doses admin	Reporting rate [†]
18-29 years old[§]	34	10,491,212	3.2 per million	248	10,212,647	24.3 per million
30-49 years old	38	20,875,708	1.8 per million	117	20,154,577	5.8 per million
50-64 years old	23	19,714,915	1.2 per million	15	18,514,388	0.8 per million
65+ years old	10	22,274,470	0.4 per million	12	19,518,324	0.6 per million

*Source of doses administered: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>; some age- and sex-specific doses administered data were imputed

[†]Reporting rate = myocarditis cases per 1 million mRNA COVID-19 mRNA second vaccine doses administered

[§]Myocarditis cases in 18-29-year-olds are confirmed cases meeting CDC's case definition

Estimated predicted COVID-19 cases prevented vs. myocarditis cases for every million mRNA vaccinations over 120 days

Females 18-29 Years

 **12,800** COVID-19 cases prevented

 **750** hospitalizations prevented

 **50** ICU admissions prevented

5 deaths prevented

3-4 myocarditis cases 

Males 18-29 Years

 **9,600** COVID-19 cases prevented

 **300** hospitalizations prevented

 **60** ICU admissions prevented

3 deaths prevented


22-27 myocarditis cases 

Estimated predicted COVID-19 cases prevented vs. myocarditis cases for every million mRNA vaccinations over 120 days

Females 30-49 Years

 **14,600** COVID-19 cases prevented

 **950** hospitalizations prevented


 **140** ICU admissions prevented
20 deaths prevented

1-2 myocarditis cases 

Males 30-49 Years

 **11,000** COVID-19 cases prevented

 **700** hospitalizations prevented

 **160** ICU admissions prevented
25 deaths prevented

5-6 myocarditis cases 

Estimated predicted COVID-19 cases prevented vs. myocarditis cases for every million mRNA vaccinations over 120 days

Females 50-64 Years

 **17,500** COVID-19 cases prevented

 **1,700** hospitalizations prevented

 **375** ICU admissions prevented

125 deaths prevented

1 myocarditis case



Males 50-64 Years

 **14,700** COVID-19 cases prevented

 **1,900** hospitalizations prevented

 **500** ICU admissions prevented

150 deaths prevented

1 myocarditis case



Estimated predicted COVID-19 cases prevented vs. myocarditis cases for every million mRNA vaccinations over 120 days

Females 65+ Years

 **32,000** COVID-19 cases prevented

 **6,200** hospitalizations prevented

 **1,300** ICU admissions prevented

900 deaths prevented

<1 myocarditis case



Males 65+ Years

 **52,700** COVID-19 cases prevented

 **12,500** hospitalizations prevented

 **3,500** ICU admissions prevented

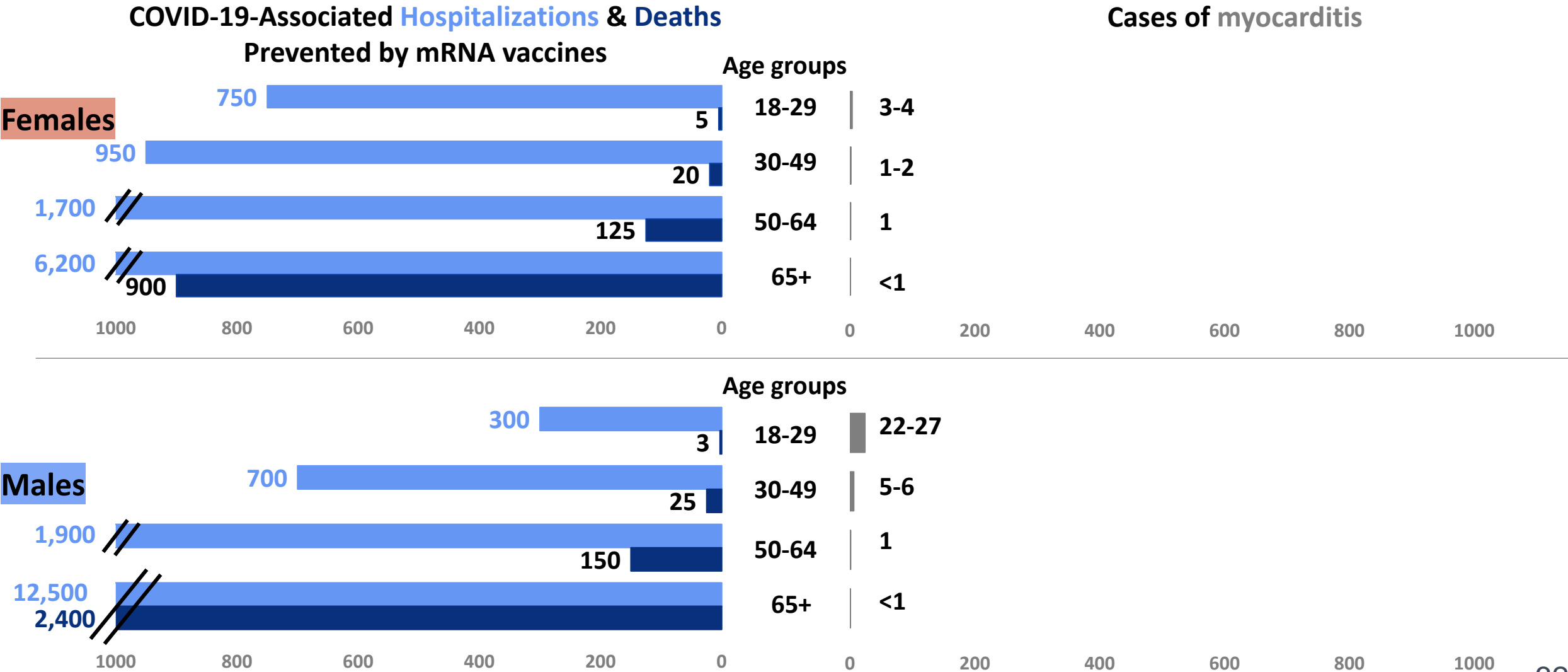
2,400 deaths prevented

<1 myocarditis case

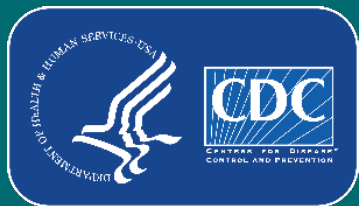


Benefits and risks after mRNA vaccine, by age group & sex

For every million doses of vaccine given with US exposure risk and hospitalization rates from June 19, 2021

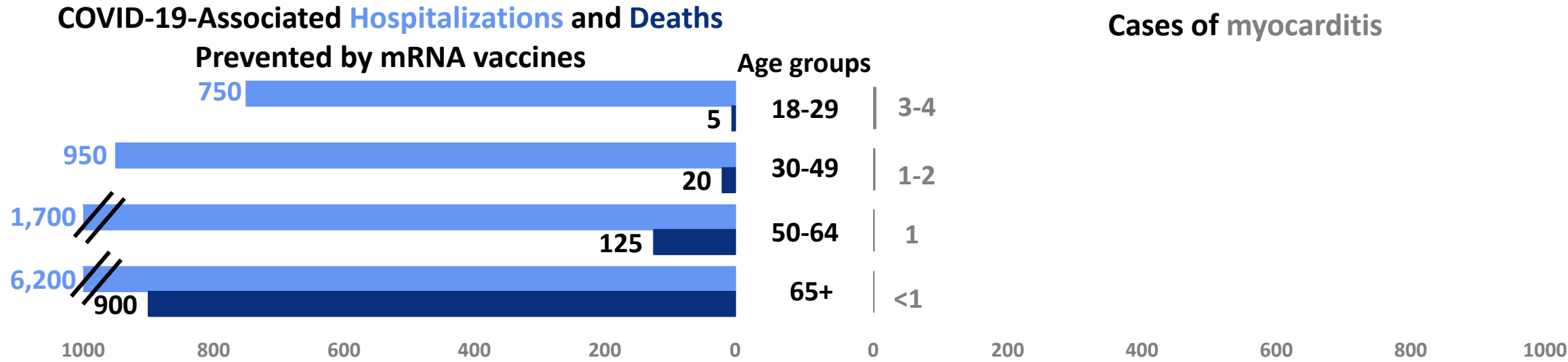
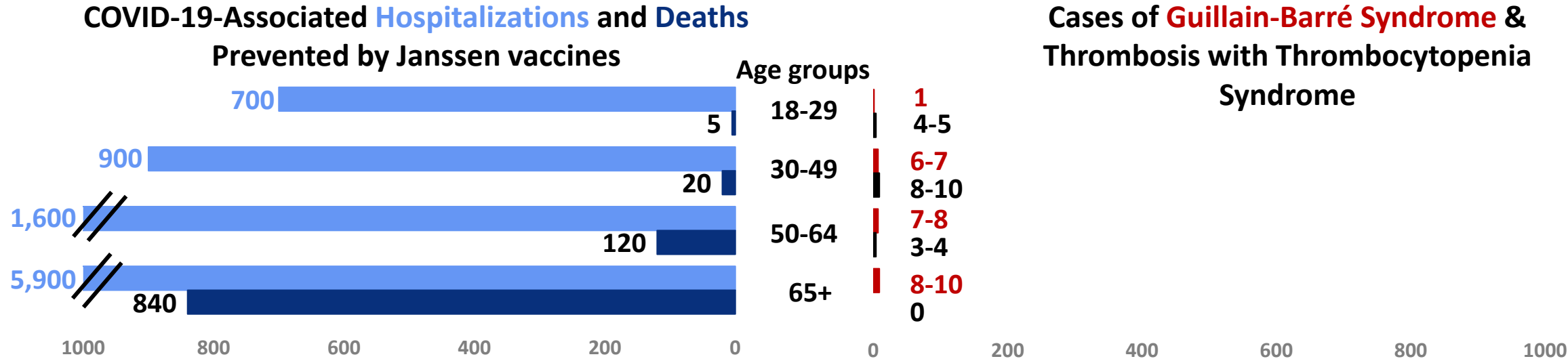


Summary



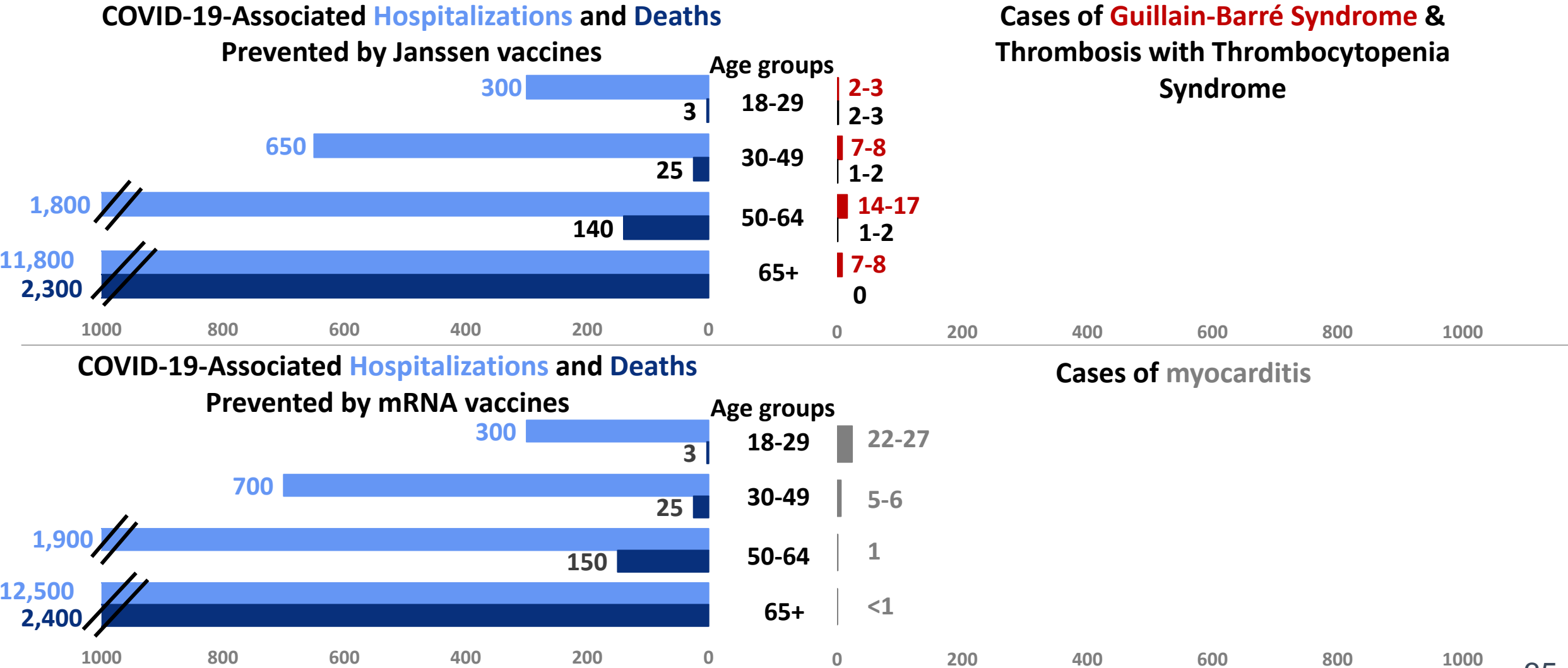
Benefits and risks after COVID-19 vaccine, by age group- females

For every million doses of vaccine given with US exposure risk and hospitalization rates from June 19, 2021



Benefits and risks after COVID-19 vaccine, by age group- males

For every million doses of vaccine given with US exposure risk and hospitalization rates from June 19, 2021



Benefits and risks after COVID-19 vaccine, by age group & sex

For every million doses of vaccine given with US exposure risk and hospitalization rates from June 19, 2021

	Janssen COVID-19 vaccine						mRNA COVID-19 vaccines			
Age	Prevented COVID-19 Outcomes			GBS Cases	TTS Cases		Prevented COVID-19 Outcomes			Myocarditis Cases
	Hospitalization	ICU	Death				Hospitalization	ICU	Death	
FEMALES										
18-29 years	700	50	5	1	4-5		750	50	5	3-4
30-49 years	900	140	20	6-7	8-10		950	140	20	1-2
50-64 years	1600	350	120	7-8	3-4		1,700	375	125	1
65+ years	5,900	1250	840	8-10	0		6,200	1300	900	<1
MALES										
18-29 years	300	60	3	2	2-3		300	60	3	22-27
30-49 years	650	150	25	7-8	1-2		700	160	25	5-6
50-64 years	1,800	480	140	14-17	1-2		1,900	500	150	1
65+ years	11,800	3300	2300	7-8	0		12,500	3500	2400	<1

Potential harms reported overall after COVID-19 vaccination

Janssen vaccine

**Thrombosis with
thrombocytopenia
syndrome:**

3.0 cases
per million doses
among adults

**Guillain-Barré
syndrome:**

7.8 cases
per million doses
among adults

mRNA vaccines

Myocarditis:

3.5 cases
per million doses
among adults

- Risk for each potential harm varies by age and by sex

Limitations of benefit-risk estimates

- Benefits of vaccination likely even greater than shown
 - Model uses current case estimates; does not account for underreporting or rising case counts
 - Benefits are estimated over 120 days following vaccination, but protection likely lasts longer
 - Does not account for post-COVID-19 conditions
- Some hospitalizations (COVID-NET) may be related to diagnoses other than COVID-19
- Vaccine efficacy from clinical trials rather than real-world data
- Crude numbers of potential harms were used for some estimates

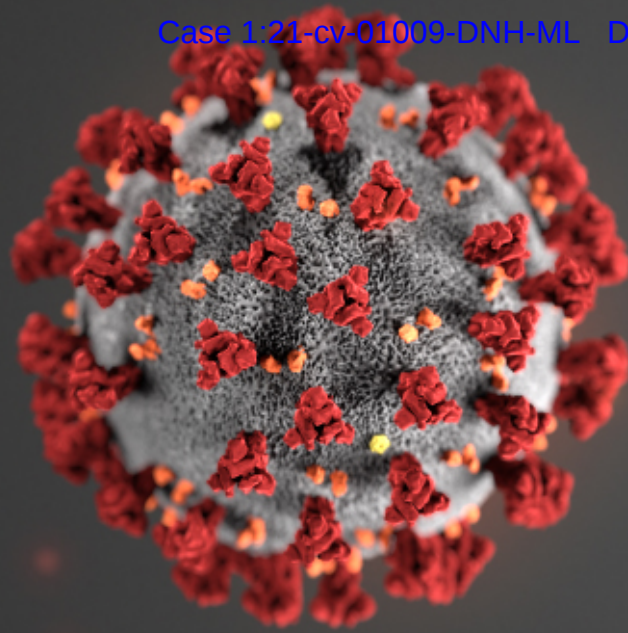
Benefit-risk interpretation and summary

- An assessment of the individual benefits and individual risks of vaccination is an important tool to help inform vaccination policy
- **This assessment demonstrates that the benefits of COVID-19 vaccination far outweigh the potential risks**
- The relative balance of benefits-risks varies by age/sex



Acknowledgements

- Danielle Moulia
- Stephen Hadler
- Nicole Reisman
- Kathleen Dooling
- Sara Oliver
- Sarah Mbaeyi
- Megan Wallace
- Julia Gargano
- Lauri Hicks
- Jack Gersten
- Mary Chamberland
- Eddie Shanley
- Monica Godfrey
- Heather Scobie
- Kevin Chatham-Stevens
- Amanda Cohn
- Tom Shimabukuro
- John Su
- Lauri Markowitz
- Melinda Wharton
- Vaccine Safety Team
- Epidemiology and Surveillance Task Force
- Vaccine Task Force



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

